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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,735	11/30/2006	Lawrence M. Blatt	INTM-019/01US 095185-2162	2009

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

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03/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/555,735	BLATT, LAWRENCE M.	
	Examiner	Art Unit	
	ZACHARY C. HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

Claims 1-20 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-5, drawn to a synthetic CXCR3 ligand and compositions comprising said ligand.

Group II, claims 6-11, drawn to a polynucleotide encoding a CXCR3 ligand, an expression vector comprising said polynucleotide, a host cell comprising said polynucleotide or vector and a method for producing a CXCR3 ligand.

Group III, claim 12, drawn to an antibody that binds to a synthetic CXCR3 ligand.

Group IV, claims 13-17 and 20, in so far as they are drawn to a method of treating a fibrotic disease comprising administering a synthetic CXCR3 ligand.

Group V, claims 18-20, in so far as they are drawn to a method of reducing tumor growth comprising administering a synthetic CXCR3 ligand.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-V appears to be that they all relate to a "synthetic CXCR3 ligand". Groups IV and V encompasses methods of use of any "synthetic CXCR3 ligand". The term "synthetic" is not provided with a limiting definition in the specification, and therefore Groups IV and V broadly encompass use of any CXCR3 ligand that is not produced naturally, i.e. any CXCR3 ligand made by the hand

of man. Such includes recombinantly produced CXCR3 ligands, such as recombinantly produced IP-10, I-TAC or Mig. Groups I-III are limited in scope to CXCR3 ligands encompassed by claims 1 or 3. However, the prior art teaches a synthetic CXCR3 ligand that falls within the scope of claim 1. Specifically, claim 1 broadly encompasses any CXCR3 ligand comprising acid one sub-sequence from IP-10 and one subsequence from I-TAC. The specification teaches that either sub-sequence may be as small as two amino acids in length (see pg 13, ¶ 56). The claim broadly encompasses any polypeptide of at least 70 amino acids comprising the required subsequences. Mack et al, U.S. Patent Application Publication 2003/0017979, published 1/23/03, filed 9/5/01, and claiming priority to 3/10/00 (cited on the 6/14/07 IDS) teaches synthetic polypeptides comprising I-TAC (¶ 29) and an antibody that binds to CD3 (¶ 30). As shown in ¶ 210, the anti-CD3 antibody comprises the amino acid sequence, "KLE" (see residues 485-487 of SEQ ID NO: 18). The ligand IP-10 comprises the same "KLE" sequence (see residues 48-50 of IP-10 in Figure 2). Thus, the fusion protein taught by Mack et al comprises an I-TAC subsequence and an IP-10 subsequence. Such a protein meets all of the limitations of a synthetic CXCR3 ligand of each of Groups I-V. Therefore, the technical feature linking the inventions of Group I-V does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

Elections of species

In addition to the above restriction requirement, 1 or 2 elections of species are also required (depending on which group is elected) as follows:

(I) Each Group (I-V) contains claims directed to more than one species of "synthetic CXCR3 ligand" of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: (1) SEQ ID NO: 1, (2) SEQ ID NO: 2, (3) SEQ ID NO: 3; (4) SEQ ID NO: 15, (5) SEQ ID NO: 16, (6) SEQ ID NO: 17, (7) SEQ ID NO: 18 and (8) SEQ ID NO: 19 and (9) SEQ ID NO: 20.

The claims are deemed to correspond to the species in the following manner:
1. Claims 1, 5, 6, 8-20 are generic to each species.
(It is noted that claim 1 broadly encompasses the full scope of claim 3).
2. Claim 2 recites species 4-9 as a Markush-type group.
3. Claim 3 is generic to species 1-3.
4. Claim 4 recites species 1-3 as a Markush-type group.
5. Claim 7 recites species 1-9 as a Markush-type group.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species of synthetic CXCR3 ligand is a discrete molecule with a unique amino acid sequence. Lack of unity is shown because these ligands lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(II) If Group IV is elected, the following election of species is also required. Group II contains claims directed to more than one species of "fibrosis" of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows: (1) pulmonary fibrosis; (2) liver fibrosis; (3) renal fibrosis; (4) cardiac fibrosis; and (5) scleroderma.

The claims are deemed to correspond to the species in the following manner:
1. Claims 13 and 20 are generic to each species.
2. Claims 14-16 correspond to species 1.
3. Claim 17 recites each of species 2-5 as a Markush-type group.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species of fibrosis occurs in a structurally different tissue of the human body. Lack of unity is shown because these diseases lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(III) If Group V is elected, the following election of species is also required. Group II contains claims directed to more than one species of "anti-neoplastic agent" of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows: (1) alkylating agent; (2) nitrosurea; (3) antimetabolite; (4) antitumor antibiotic; (5) plant (vinca) alkaloid; (6) taxane and (7) steroid hormone.

The claims are deemed to correspond to the species in the following manner:
1. Claim 18 is generic to each species.
2. Claim 19 recites each of species 1-7 as a Markush-type group.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species of anti-neoplastic agent is a discrete molecule with a unique structure. Lack of unity is shown because these agents lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Applicant is required, in reply to this action, to elect a single species of ligand, and if Group IV or V is elected, a single species of fibrosis or anti-neoplastic agent, which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646